# Interstate Shellfish Sanitation Conference

# *Task Force II Report*

## 2013 Biennial Meeting
## January 25 – January 31, 2014

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***Board Consultant***

**Dave Wiggins**
***FDA***

**Angela Ruple**
***NOAA***

***The St. Anthony Riverwalk Hotel***
***"a national historic landmark"***

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| **Proposal Subject:** | Identification of Wet Stored Shellstock |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Model Ordinance<br>Chapter X. General Requirements for Dealers<br>@ .05 Shellstock Identification B. Tags (2) |
| **Text of Proposal/ Requested Action** | .05 B. (2) The dealers tag…<br><br>(a) The dealer's name…<br>(b) The dealer's certification…<br>(c) The original shellstock …<br>(d) The date of harvest…<br>(e) If depurated …<br>(f) The most precise…<br>(g) **When the shellstock has been transported from the original area and wet stored in another approved growing area within the same state for at least two weeks, the dealer will:**<br>**(i) use the date shellstock was harvested from the last growing area as the harvest date;**<br>**(ii) identify the last growing area as the harvest location.**<br>~~(g)~~ **(h)** When the shellstock has been transported across state lines…<br>~~(h)~~ **(i)** The type and quantity …<br>~~(i)~~ **(j)** The following statement…<br>~~(j)~~ **(k)** All shellstock intended… |
| **Public Health Significance:** | There is no guidance in the Model Ordinance on tagging shellstock that is moved from one growing area to another within the same state. After 2 weeks in a growing area, the shellstock would have the characteristics of the new growing area and the product should be tagged appropriately. This will facilitate product recall and trace backs in the event of human illnesses. |
| **Cost Information (if available):** | None |
| **Action by 2003 Task Force II** | Recommended referral of Proposal 03-204 to the appropriate committee as determined by the Conference Chairman. |
| **Action by 2003 General Assembly** | Adopted recommendation of 2003 Task Force II. |
| **Action by USFDA** | Concurred with Conference Action. |
| **Action by 2005 Post-Harvest Processing Committee** | Recommended adoption of Proposal 03-204 with the following change to (g):<br><br>(i) use the date shellstock was harvested from the last most recent growing area as the harvest date;<br>(ii) identify the last most recent growing area as the harvest location. |

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| **Action by 2005 Task Force II** | Recommended referral of Proposal 03-204 to appropriate committee as determined by the Conference Chairman. |
| **Action by 2005 General Assembly** | Adopted recommendation of 2005 Task Force II. |
| **Action by USFDA** | Concurred with Conference action. |
| **Action by 2007 Traceability/PHP Committees** | Recommended no action on Proposal 03-204. Rationale – No scientific information has been provided to support the suggestion that shellstock harvested and wet stored for a specified period of time in a site other than the original harvest site takes on the characteristics of the wet storage area. |
| **Action by 2007 Task Force II** | Recommended referral of Proposal 03-204 back to the Post Harvest Processing Committee with direction to address confusion over whether activity is wet storage, relay, or transplanting under aquaculture and to secure whatever science is available relative to length of time in growing area to take on new characteristics of that growing area. |
| **Action by 2007 General Assembly** | Adopted recommendation of 2007 Task Force II. |
| **Action by USFDA** | December 20, 2007<br>Concurred with Conference action. |
| **2011 NOTE:** | The only pending action associated with this proposal will be a report from FDA. The report will be shared with the membership when available. |
| **Action by 2011 Task Force II** | Recommended no action on Proposal 03-204.<br><br>Rationale: No additional information has been provided on this proposal. |
| **Action by 2011 General Assembly** | Adopted recommendation of 2011 Task Force II on Proposal 03-204. |
| **Action by FDA February 26, 2012** | Concurred with Conference action on Proposal 03-204. |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 03-204.<br>Rationale: No additional information is available. |

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| **Proposal Subject:** | Post-Harvest Handling |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Model Ordinance<br>Definitions and New Chapter XVII. |
| **Text of Proposal/ Requested Action** | Action #1<br><br>Add a new definition to B. Definition of Terms for Post-Harvest Handling and renumber Definitions Section accordingly.<br><br>Post-Harvest Handling means a control(s) employed by a dealer to further reduce, beyond controls currently in place under the NSSP, the post-harvest growth of naturally occurring pathogens for the purposes of handling product outside of as an alternative to the Authority's existing NSSP management plans.<br><br>Action #2:<br><br>Add a new chapter to the NSSP Guide Section II. Model Ordinance as follows:<br><br>Chapter XVII. Post-Harvest Handling<br><br>A. If a dealer elects to use a post-harvest handling control(s) to reduce the levels of post-harvest growth of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall:<br>(1) Have a HACCP plan (approved by the Authority) for the control(s) that reduces post-harvest growth of the target pathogen(s).<br>(a) The dealer must validate that the post-harvest handling control(s) reduces the post-harvest growth of naturally occurring pathogen(s). The validation study must be approved by the State Shellfish Control Authority with FDA concurrence.<br>(b) The ability of the post-harvest handling control(s) to reliably achieve the appropriate reduction in post-harvest growth of the target pathogen(s) shall be routinely verified at a frequency determined by the State Shellfish Control Authority.<br>(2) Package and label all shellfish in accordance with the requirements of this Ordinance.<br>(3) Keep records in accordance with Chapter X. 07. |
| **Public Health Significance:** | The changes recommended by this proposal provide added opportunities for shellfish dealers to meet the required State Control Plans for naturally occurring pathogens. |
| **Cost Information (if available):** | |
| **Action by 2009 Task Force II:** | Recommended referral of Proposal 09-231 to an appropriate committee as determined by the Conference Chairman. |
| **Action by 2009 General Assembly** | Adopted recommendation of 2009 Task Force II on Proposal 09-231. |

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| **Action by USFDA 02/16/2010** | Concurred with Conference action on Proposal 09-231. |
| **Action by 2011 Post Harvest Processing Committee** | Recommended no action on Proposal 09-231.<br><br>Rationale: The proposed new definition and new chapter are not necessary because the State *Vibrio* Management Plans already allow handling practices to reduce levels of naturally occurring pathogens. The recommended changes are adequately addressed in the Model Ordinance. |
| **Action by 2011 Task Force II** | Recommended referral of Proposal 09-231 to an appropriate Committee as determined by the Conference Chairman with instructions that the Committee establish validation protocols for activities that reduce levels of naturally occurring pathogens so that a dealer can work outside the Authority's *Vibrio* Management Plan. Additionally, the Committee is charged with ensuring the Post-Harvest Handling (PHH) definition and section in Chapter XVII is consistent so that they are directing a process that reduces levels not just growth.<br><br>The intent of Task Force II is that Post Harvest Handling activities are not intended to be used to support labeling claims. |
| **Action by 2011 General Assembly** | Adopted recommendation of 2011 Task Force II on Proposal 09-231. |
| **Action by FDA February 26, 2012** | Concurred with Conference action on Proposal 09-231. |
| **Action by 2013 Post Harvest Processing Committee** | The Post-Harvest Processing Committee recommended:<br><br>1. No action on proposal 09-231 as written.<br>2. Change the title of Model Ordinance Chapter XVI, Post-Harvest Processing to "Processes and Procedures for Pathogen Reduction" in order to include pathogen reduction processes that are not associated with labeling claims, which was the intent of Proposal 09-231.<br>3. Add a new section to the newly titled Chapter XVI (Recommendation 2) to be titled "Pathogen Reduction Processes that are not associated with Labeling Claims."<br>4. The committee recommends that a work group be established to develop language for the new section of Chapter XVI and report the findings to the appropriate committee as determined by the Conference Chairman. It is further recommended that the work group meet quarterly until the new section is complete so that it can be submitted as a proposal at the next ISSC meeting.<br>5. Request the Conference Chairman to appoint an appropriate work group or committee to work with FDA to establish target levels for pathogen reduction processes that do not require labeling that will achieve the required risk reduction goals. (The intent of the committee is to use the information developed by this workgroup to determine if additional validation protocols are needed.)<br><br>Recommendation 5 should be done as soon as possible to allow validation protocols to be developed as necessary |

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| **Action by 2013 Task Force II** | Recommends referral of Proposal 09-231 back to Committee with instructions to continue the work on the proposal which includes recommendations 2. – 5. as a charge to the Committee; with further instructions that recommendation 5. should be completed as soon as possible to allow validation protocols to be developed as necessary. |

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| **Proposal Subject:** | *Vibro vulnificus* Risk Management of Oysters |
| **Specific NSSP Guide Reference:** | ISSC Constitution, Bylaws, and Procedures Article IV.<br>Section II Model Ordinance, Chapter II Risk Assessment and Risk Management<br>@.01 Outbreaks of Shellfish Related Illnesses<br>@.04 *Vibrio vulnificus* Risk Management for Oysters<br>Section IV. Guidance Documents, Chapter IV. Naturally Occurring Pathogens |
| | **Refer to *Proposals for Consideration at the 2013 Biennial Meeting*** |
| **Action by 2013 Vibrio Management Committee** | Recommended adoption of the following Vibrio Management Committee (VMC) recommendations:<br><br>1. Develop a database to input the *V.v.* Illness Review Committee information.<br><br>2. Develop criteria for verifying reduction in harvest for raw consumption and the percentage of post-harvest processed product. Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this either |
| **Action by 2013 Task Force II** | Recommends adoption of VMC recommendation No. 1 to develop a database to input the *V.v.* Illness Review Committee information.<br><br>Recommends no action on recommendation No. 2 to develop criteria for verifying reduction in harvest for raw consumption and the percentage and refer to ISSC Executive Office. Rationale: The Executive Office has had very little success in identifying approaches for obtaining this kind of information and the VMC had no suggestions on how to achieve this. |

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| **Proposal Subject:** | Transportation and Critical Control Points |
| | **Refer to *Proposals for Consideration at the 2013 Biennial Meeting*** |
| **Specific NSSP Guide Reference:** | Section II Model Ordinance, Chapter IX. Transportation<br>Section II Model Ordinance, Chapter XI. Shucking and Packing<br>Section II Model Ordinance, Chapter XII. Repacking of Shucked Shellfish<br>Section II Model Ordinance, Chapter XIII. Shellstock Shipping<br>Section II Model Ordinance, Chapter XIV. Reshipping |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal11-201-B as amended.<br><br>Chapter VIII. @.02<br>I. Shellstock intended for a validated pathogen reduction process where refrigeration would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) is exempt from the requirements in Chapter VIII. @.02 A. (1) and (2).<br><br>Chapter VIII. @.02<br>E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements. For states that establish and limit harvest times that assure compliance with the times outlined in the matrix of Chapter VIII. @.02 A. (3) recording the time harvest begins is not required. |

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| **Proposal Subject:** | Review of CDC *V.p.* Illness Information |
| **Specific NSSP Guide Reference:** | Section II Model Ordinance Chapter II @.05 |
| **Text of Proposal/ Requested Action** | N/A |
| **Public Health Significance:** | The number of cases of *V.p.* associated with consumption of shellfish reported to the CDC by states in 2009 shows a significant increase from previous years. There were not any large outbreaks that occurred during the year, but the total number of reported cases was the second highest since 1998, which included cases from outbreaks associated with product from all three coasts. The large number of 2009 cases, in the absence of a large outbreak, suggests that the ISSC needs to review current CDC *V.p.* illness information and determine the adequacy of current control strategies in the NSSP.<br><br>The VMC and the ISSC Executive Board briefly discussed the 2009 reported illnesses and agreed that a *V.p.* subcommittee should discuss the CDC reported information and make appropriate recommendations for VMC review. The purpose of this proposal is to notify the interested parties that change to the controls of Chapter II @.05 may be discussed at the ISSC 2011 Biennial Meeting. |
| **Cost Information (if available):** | |
| **Action by 2011 Task Force II** | Recommended adoption of Vibrio Management Committee recommendation on Proposal 11-206 to refer to an appropriate committee as determined by the Conference Chairman. |
| **Action by 2011 General Assembly** | Adopted the recommendation of Task Force II on Proposal 11-206. |
| **Action by FDA February 26, 2012** | Concurred with Conference action on Proposal 11-206. |
| **Action by 2013 Vibrio Management Committee** | The Vibrio Management Committee recommended that FDA request CDC to be present at Task Force II to answer questions on their data including, (1) does the data include exposures to other foods especially to crustaceans, (2) does data include actual cases or under-reporting factors, and (3) explanation of the *V.p.* death data |
| **Action by 2013 Task Force II** | Recommends referral of Proposal 11-206 back to committee. Task Force II further recommends that CDC be asked to participate as a member of the committee. |

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| **Proposal Subject:** | *Vibrio cholera* |
| **Specific NSSP Guide Reference:** | Section II Model Ordinance Chapter II Risk Assessment and Risk Management |
| **Text of Proposal/ Requested Action** | |
| **Public Health Significance:** | In April of 2011, the State of Florida reported a shellfish related illness outbreak associated with a toxigenic strain of *Vibrio cholera* O75. Current knowledge of *Vibrio cholera* O75 suggests that this toxigenic strain can be pollution oriented or naturally occurring. The National Shellfish Sanitation Program (NSSP) requirements for addressing outbreaks are different for pollution related hazards and naturally occurring hazards. The determination of whether an outbreak of *Vibrio cholera* O75 is pollution related or naturally occurring is difficult and creates management problems for public health officials and shellfish control authorities.<br><br>Procedure XIV of the ISSC Constitution, Bylaws, and Procedures outlines steps for addressing pathogens and deleterious substances newly recognized in shellfish. The purpose of this proposal is to provide notice to the membership that FDA and the ISSC will be discussing appropriate steps to address the *Vibrio cholera* situation. If recommendations for NSSP controls are developed for consideration at the 2011 Biennial Meeting, the ISSC membership will be notified. |
| **Cost Information (if available):** | |
| **Action by 2011 Task Force II** | Recommended adoption of the Pathogen Review Committee recommendation to refer Proposal 11-207 to an appropriate committee as determined by the Conference Chairman. |
| **Action by 2011 General Assembly** | Adopted the recommendation of Task Force II on Proposal 11-207. |
| **Action by FDA February 26, 2012** | Concurred with Conference action on Proposal 11-207. |
| **Action by 2013 Pathogen Review Committee** | The Pathogen Review Committee recommended that *Vibrio cholera* O75 should be treated as a naturally occurring pathogen unless the Authority determines there is evidence of association with pollution. |
| **Action by 2013 Task Force II** | Recommends adoption of Pathogen Committee recommendation on Proposal 11-207 and further recommends wording be placed in the NSSP Model Ordinance as determined by the Executive Board. |

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| **Proposal Subject:** | Aquaculture Facility Inspection Frequency |
| **Specific NSSP Guide Reference:** | Section II Model Ordinance Chapter VI. Shellfish Aquaculture<br>@.01 General C. |
| **Text of Proposal/ Requested Action:** | The Authority shall inspect commercial aquaculture systems at least annually. |
| **Public Health Significance:** | Moving to a lesser number of inspections per year will not impact public health. |
| **Cost Information (if available):** | States are facing serious budget restrictions. Some find the current requirement for semiannual inspections to be excessive and not in furtherance of public health. States may maintain a higher frequency of inspection if they choose while allowing other states to decrease the frequency. States should, within limits, be able to determine priorities and allocate resources accordingly. |
| **Action by 2011 Task Force III** | Recommended referral of Proposal 11-208 to the appropriate committee as determined by the Conference Chairman. |
| **Action by 2011 General Assembly** | Adopted the recommendation of Task Force III on Proposal 11-208. |
| **Action by FDA February 26, 2012** | Concurred with Conference action on Proposal 11-208. |
| **Action by 2013 Aquaculture Facility Inspection Committee** | The Committee recommended no action on Proposal 11-208. |
| **Action by 2013 Task Force II** | Recommends adoption of the Aquaculture Facility Inspection Committee recommendation of no action on Proposal 11-208.<br><br>Rationale: Deficiencies will be resolved by action on another proposal. |

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| **Proposal Subject:** | Reducing the Risk of Vibrio Illnesses |
| **Specific NSSP Guide Reference:** | NSSP Guide for the Control of Molluscan Shellfish |
| **Text of Proposal/ Requested Action** | A Vibrio workshop was held in Dauphin Island, Alabama in November 2012 to discuss possible solutions for addressing illness risks. State Shellfish Control Authority representatives, Vibrio researchers, and the USFDA participated in the two-day workshop. The participants identified several topics (listed below) that are related to Vibrio controls. These topics should be addressed by the collective participants of the ISSC. The purpose of this proposal is to request the ISSC Executive Board work collaboratively with the USFDA to address the information gaps that are obstacles to identifying effective control strategies for reducing the risk of illness associated with Vibrioses.<br><br>**Requested Action Items:**<br><br>1. Rewrite Chapter II. Risk Assessment *V.p.* (section 05).<br>2. Incorporate salinity (and other environment factors?) into *V.v.* and *V.p.* risk calculators.<br>3. Develop protocol for validating the effectiveness of non-labeling PHPs<br>4. Develop protocol for ensuring that growing/harvest/handling (production) practices do not increase risk of Vibrio illness.<br>5. Request FDA to develop sampling protocol for closing versus reopening growing areas after outbreaks including the development of resources to sustain the present capabilities<br>6. Develop new labeling/tagging system for oysters produced under conditions achieve equivalent levels as validated PHP (for labeling), including validation protocol<br>7. ISSC request FDA to reexamine risk assessments and risk calculators (*V.p.* and *V.v.*)<br>8. ISSC request FDA to reexamine illness and landings data to determine observed risk per serving<br>9. Develop the process for using local data to refine calculators to more accurately reflect risk in the region or state<br>10. Determine how best to estimate national consumption patterns for molluscan bivalves<br>11. Mega study<br>12. ISSC request FDA technical assistance for enhancing state vibrio programs (data management, laboratory support, think tank, BMPs, evaluation of effectiveness of new controls, statistical support)<br>13. States request FDA assistance with developing approved method(s) to temper clams<br>14. Draft proposal for acceptance of laboratory methods validated by other accrediting bodies |
| **Public Health Significance:** | The ISSC continues to struggle with identifying practical cost effective strategies for reducing the risk of Vibrio illnesses associated with the consumption of molluscan shellfish. This proposal identifies information needs that are obstacles to the development of control strategies. |
| **Cost Information (if available):** | |
| **Research Needs** | ***The purpose of this section is to allow the submitter to identify research needs*** |

***associated with the proposal. Please use additional pages as necessary.***

**Proposed Specific Research Need/Problem to be Addressed:**

1. Is total *V.v.* a valid indicator of risk?
2. Are there differential effects of validated PHP on virulent subpopulations?
3. How do environmental factors affect levels of virulent subpopulations?
4. Compile collection of *V.v.* for future virulence research.
5. Do other species react to controls the same as *V.v.*and *V.p.*?
6. Determine relative virulence of *V.p.* subpopulations.
7. What are Vibrio (total and virulent) levels at harvest (in oysters and clams)?
8. How much Vibrio (total and virulent) growth results from the current time/temperature controls (in oysters and clams)?

**Research Priorities**

1. What information is needed to supply more tools to the "toolbox"?
2. What regional information is needed to refine risk assessments and risk calculator tools for implementation of effective control plans?
3. What is the significance of salinity to Vibrio levels in shellfish?
4. Is there a salinity/temperature matrix that determines Vibrio levels?
5. What are the key virulence factors (or combination thereof) for *V.v.* and *V.p.*?
6. Need to know dose response of different Vibrio strains and populations
7. What are the regional differences in pathogenic strains of *V.v.* and *V.p.*?
8. What is the percentage of pathogenic strains of Vibrio in growing waters?
9. Should the "viable but not culturable" state in pathogenic Vibrios be a concern?

**Please explain the relationship between the proposed research need and the program change recommended in the proposal. Support need with literature citations as appropriate.**

**Estimated Cost: $**

**Proposed Sources of Funding/Support:**

**Time Frame Anticipated:**

***For Research Guidance Committee Use Only***

**Relative Priority Rank in Terms of Resolving Research Need:**

**☐Immediate ☐ Required ☐ Valuable ☐Important**

**☐Other** Click here to enter text.

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| **Action by 2013 Task Force II** | Recommends referral of Proposal 13-200 to an appropriate committee as determined by the Conference Chairman with instruction to the committee as follows:<br><br>1. Request that FDA reexamine its risk assessments and risk calculators (*V.p.*) and (*V.v.)* and present the results to ISSC, including the factors and methodology used to calculate risk per serving.<br>2. Develop a process for using local data including regional or state illness and landings information, to more accurately reflect risk in a region or state.<br>3. Determine how best to estimate consumption patterns, including collection data regarding the number of shellfish consumed per serving, through market research, end-point consumer data, or other information gathering methods.<br>4. Evaluate existing NSSP regulations to reduce risk of Vibrio illness caused by improper handling, storing, or transportation of shellstock and the |

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| | effectiveness of existing enforcement mechanisms.<br>5. Provide recommendations to ISSC based on the results of the above study and evaluation. |

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| **Proposal Subject:** | Shellfish Plant Inspection Documentation |
| **Specific NSSP Guide Reference:** | NSSP Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @ .02. Dealer Certification F. Inspections |
| **Text of Proposal/ Requested Action** | Add new:<br><br>3. The Authority shall document deficiencies observed during the inspection. Documentation of observed deficiencies corrected during the inspection must remain on the inspection form as a complete and accurate documentation of corrections.<br>4. The Authority shall verify if observations made during a prior inspection are corrected. If an observation made during a prior inspection has not been corrected, or is a recurring observation, it must be documented on the inspection form. |
| **Public Health Significance:** | The unique nature of shellfish as a food consumed whole and raw in the form as it comes from the growing area requires the state shellfish control authority to have sufficient capacity to enforce the public health based restrictions on sanitation controls and to obtain meaningful penalties for violation of those controls. Dealer certification is intended to provide an unbroken chain of sanitation control to many shellfish from the moment of harvest to its sale at the wholesale or retail level. Dealers having major non-conformities with the NSSP Model Ordinance should not be certified. Certified dealers found to have major non-conformities should have their licenses, or permits suspended, or certifications revoked.<br><br>Dealer certification is dependent on a dealer maintaining acceptable operational and sanitary conditions and is determined through uniform inspections by standardized inspectors. State officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable Model Ordinance sanitation guidelines pertaining to the type of operation involved. Accurate documentation of observed deficiencies by the Authority is critical for maintaining and enforcing compliance with the sanitation controls in the *Guide for the Control of Molluscan Shellfish Model Ordinance.* |
| **Cost Information (if available):** | N/A |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 13-201.<br>Rationale: This proposal is adequately addressed in Model Ordinance. |

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| **Proposal Subject:** | Outbreaks of Shellfish Related Illness |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority |
| **Text of Proposal/ Requested Action** | @.01 Outbreaks of Shellfish-Related Illness.<br><br>A. When shellfish harvested within ten (10) days of each other from the same growing area are implicated in an illness outbreak involving ~~two (2)~~three (3) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:<br><br>(1) Each consumer's food history;<br>(2) Shellfish handling practices by the consumer and/or retailer;<br>(3) Whether the disease has the potential or is known to be transmitted by shellfish; ~~and~~<br>(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent~~.~~ ; and<br>(5) Harvest tags, dealer tags and shipping and receiving records to determine the origin of shellfish implicated in an illness outbreak. Copies of harvest tags, dealer tags and shipping and receiving records are to be provided to the Authority. Failure to provide accurate harvest tags, dealer tags or shipping and receiving records substantiating the origin of the shellfish would preclude the existence of an epidemiological association.<br><br>B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:<br><br>(1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.<br>(2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.<br><br>C. When the investigation outlined in Section .02 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:<br><br>(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;<br>(2) Notify receiving states, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;<br>(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the |

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| | implicated shellfish; and<br>(4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest] and no implicated product is likely to remain in the market place). |
| **Public Health Significance:** | |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-202 as substituted.<br>Chapter II. Risk Assessment and Risk Management<br>@.01 Outbreaks of Shellfish Related Illness<br>F. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.<br>(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.<br>(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area and when two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:<br>(a) Determine the extent of the implicated area; and<br>(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and<br>(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.<br>(3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) cases occurred from a single harvest date from the implicated area, The Authority shall:<br>(a) Determine the extent of the implicated area; and<br>(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and |

(c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(d) Issue a consumer advisory for all shellfish (or species implicated in the illness).

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:

(a) The area will remain closed for a minimum of seven (7) days when sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves four (4) or less cases occurring within a thirty (30) day period from the implicated area in which no two (2) cases occurred from a single harvest date from the implicated area.

(b) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area with two (2) or more cases but less than four (4) cases occurring from a single harvest date from the implicated area.

(c) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area

(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one or more of the following controls:

(a) Post-harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for Pacific Coast oysters;

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| | (b) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;<br>(c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority. |

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| **Proposal Subject:** | Annual Assessment of Shellfish Production and Utilization |
| **Specific NSSP Guide Reference:** | NSSP Section II Model Ordinance Chapter II Risk Assessment and Risk Management |
| **Text of Proposal/ Requested Action** | @ .02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production<br><br>A. The Authority shall assess annually *Vibrio vulnificus* and *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *Vibrio vulnificus* and *Vibrio parahaemolyticus* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.<br><br>B. The Authority shall determine annually, and report to the ISSC, the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species associated with Vibrio illnesses, including a volume breakdown by utilization type (raw, shucked, PHP, etc.). |
| **Public Health Significance:** | *Vibrio parahaemolyticus* and *V. vulnificus* control plans are based on risk per serving as determined by risk calculators developed by FDA. The predicted risk is applicable to consumption of raw oysters as this product use is assumed to present the greatest risk and is associated with the majority of seafood related illnesses. However predicted risk per serving levels in raw or half-shell oysters cannot currently be validated using observed data because only total landings are reported. The risk assessments assume that 50% of oysters are consumed raw but this can vary greatly from state to state and seasonally. A breakdown of total landings by product utilization would allow more accurate assessment of the associated risk of the various product categories. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-203 as amended.<br><br>@ .02 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production<br><br>A. The Authority shall assess annually *Vibrio vulnificus* and *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *Vibrio vulnificus* and *Vibrio parahaemolyticus* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.<br><br>B. The Authority shall determine annually, and report to the ISSC, the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species associated with Vibrio illnesses, including, if available, a volume breakdown by utilization type (raw, shucked, PHP, etc.). |

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| **Proposal Subject:** | Vibrio Control Plans |
| **Specific NSSP Guide Reference:** | Chapter II @.05 *Vibrio vulnificus* Control Plan<br>Chapter II @.06 *Vibrio parahaemolyticus* Plan |
| **Text of Proposal/ Requested Action** | **@.05 *Vibrio ~~vulnificus~~* Control Plan ~~(Effective January 1, 2012)~~**<br><br>A. Risk Evaluation<br>Each shellfish producing State that is not currently implementing a *Vibrio ~~vulnificus~~* (*V.v.*) ~~control~~ control plan for purposes of controlling the risk of *Vibrio vulnificus* (*V.v.*) and/or *Vibrio parahaemolyticus (V.p.)* shall conduct a *Vibrio ~~vulnificus~~* risk evaluation annually. The evaluation ~~shall~~should consider factors deemed appropriate by the State Authority for effectively assessing whether or not~~each of the following factors, including seasonal variations in the factors, in determining~~ the risk of *Vibrio vulnificus* or *Vibrio parahaemolyticus* infection from the consumption of shellfish harvested from the State's growing waters is reasonably likely.<br>(1) In conducting the risk evaluation the State Authority may ~~will at a minimum~~ consider any number of factors, for example~~the following~~:<br>(a) The number of *Vibrio vulnificus and Vibrio parahaemolyticus* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and<br>(b) Levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* in the growing waters and in shellfish, to the extent that such data exists; and<br>(c) Levels of tdh+ and trh+ *Vibrio parahaemolyticus* in the growing area to the extent that such data exists; and<br>(d) The water temperatures in the growing area; and<br>(e) The air temperatures in the growing area; and<br>(f) Salinity in the growing area; and<br>(g) Harvesting techniques in the growing area; and<br>(h) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.<br><br>B. The State shall develop a *Vibrio* Contingency Plan should the risk evaluation indicate:<br>(1) Any etiologically confirmed shellfish-borne *Vibrio vulnificus* or *Vibrio parahaemolyticus* illness from the growing waters of that State but the number of cases does not reach the illness threshold established in Chapter II @.05 D or E; and<br>(2) Information on Levels of *Vibrio vulnificus* or *Vibrio parahaemolyticus*, if available, in the growing waters or in shellfish that is reasonably likely to cause an illness;<br><br>BC. States which have previously met the illness threshold for *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* requiring a *Vibrio ~~vulnificus~~* Control Plan will continue to maintain and implement a *Vibrio ~~vulnificus~~* Control Plan~~.~~<br><br>CD. All States not currently implementing a *Vibrio ~~vulnificus~~* Control Plan shall develop and implement a *Vibrio ~~vulnificus~~* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *Vibrio vulnificus* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that state within |

the previous ten (10) years.

E. All states not currently implementing a *Vibrio* Control Plan shall develop and implement a *Vibrio* Control Plan should the risk evaluation indicate that the State has a shellfish growing area that was the source of oysters or hard clams (*Mercenaria mercenaria*) that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years.

~~D. The State shall develop a *Vibrio vulnificus* Contingency Plan should the risk evaluation indicate:~~

~~(1) Any etiologically confirmed shellfish borne *Vibrio vulnificus* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.04 C.; and~~

~~(2) Information on Levels of *Vibrio vulnificus*, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;~~

EF. *Vibrio* Control Plan

(1) The *Vibrio ~~vulnificus~~* Control Plan shall include the following:

~~(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:~~

~~(i) The water temperatures in the area; and~~

~~(ii) The air temperatures in the area; and~~

~~(iii) Salinity in the area; and~~

~~(iv) Harvesting techniques in the area; and~~

(v) Other factors which affect risk which can be used as a basis for reducing risk.

(~~b~~a) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* illness:

(i) Labeling oysters and/or hard clams, "For shucking by a certified dealer", when the ~~Average Monthly Maximum W~~water ~~T~~temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold ~~70°F~~.

(ii) Subjecting all oysters and/or hard clams intended for the raw, half-shell market to Authority approved post-harvest processing when the ~~Average Monthly Maximum W~~water ~~T~~temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold~~70°F~~.

(iii) Cooling oysters and/or hard clams to 50°F within one hour of harvest when the water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.

~~Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.*~~

~~plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Wwater Ttemperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator.~~

~~(iv)~~ Prohibiting the harvest of oysters and/or hard clams when water temperature exceeds the temperature associated with Vibrio illnesses that caused the State to meet the illness threshold.~~The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.~~

(2) Control Plan Evaluation

(a) ~~In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~The State Authority will conduct an evaluation of the plan. At a minimum the Authority will consider:

(i) Changes in the annual number of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* cases associated with the State's growing waters.

(ii) Environmental changes which could affect total *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) ~~The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.~~ For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation to determine the following:

(i) Authority compliance with the *Vibrio* Risk Evaluation as required in Chapter II @ .05 A.

(ii) For States required to develop and implement a *Vibrio* Control Plan, compliance with Control Plan requirements of Chapter II @ .05 F. (1). The evaluation shall determine:

a. Did the Authority implement one or more of the control measures required in Chapter II @ .05 F. (1)?

(iii) For Authorities required to develop *Vibrio* Contingency Plans the evaluation shall determine:

a. Did the risk evaluation indicate the need for a Contingency Plan?

b. Does the plan include the regulatory steps to be implemented should the number of illnesses reach the illness threshold requiring implementation of a Vibrio Control Plan?

(c) The results of the State and USFDA evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures.

FG. Contingency Plan

(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *Vibrio*~~.v~~. Control Plan.

(2) Contingency Plan Evaluation

In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

~~**@.06 *Vibrio parahaemolyticus* Control Plan**~~

~~A. Risk Evaluation.~~

~~Every State from which oysters and/are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters and/ harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)~~

~~(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and~~

~~(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and~~

~~(3) The water temperatures in the area; and~~

~~(4) The air temperatures in the area; and~~

~~(5) Salinity in the area; and~~

~~(6) Harvesting techniques in the area; and~~

~~(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.~~

~~B. Control Plan~~

~~(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters and/ harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or~~

~~(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control~~

~~Plan are:~~

~~(a) Waters bordering the Pacific Ocean : 60°F.~~

~~(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.~~

~~(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.~~

~~(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;~~

~~(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or~~

~~(3) If a State has a shellfish growing area that was the source of oysters and/that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.~~

~~(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:~~

~~(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.~~

~~(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:~~

~~(i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;~~

~~(ii) Closing the area to oyster harvest;~~

~~(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;~~

~~(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;~~

~~(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;~~

~~(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.*~~

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| | ~~illness is no longer reasonably likely to occur, as approved by the Authority.~~<br><br>~~(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.~~<br><br>~~(d) Evaluate the effectiveness of the Plan.~~<br>~~(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.~~<br>~~(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.~~<br>~~C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.~~ |
| **Public Health Significance:** | While *Vibrio parahaemolyticus* and *Vibrio vulnificus* Control plans (VPCP and VVCP) rely primarily on time and temperature controls to reduce post-harvest vibrio growth, the controls implemented vary widely from state to state. States requiring *V.v.* controls generally must implement more restrictive harvest controls than states which only require *V.p.* control plans. Additionally, risk per serving standards associated with VVCP require corrective actions that are absent in VPCP. This disparity creates an economic advantage for industry in states with less stringent requirements and favors higher production of more risky product. This may partially explain the increases in reported *V.v.* illnesses in recent years while *V.v.* cases have remained relatively static over this same period. Post-harvest growth increases the risk of *V.p.*, *V.v.* and likely other Vibrio spp. and shall be prevented by any reasonable means. Enforcement of current time and temperature controls is problematic as it is difficult to determine when the product was harvested. Immediate cooling would prevent any vibrio growth and maintain the vibrio levels at harvest providing enhanced public health protection relative to the current control plans. Immediate cooling would also facilitate enforcement and improve compliance. This approach is consistent with Codex Guidance for bivalve mollusks and industry cooling practices with other seafood products that are inherently less risky. Environmental monitoring with the current capabilities and capacity is not an effective means for mitigating vibrio risk. While immediate cooling is not as effective as Post Harvest Processing (PHP) or closures, it is far less disruptive to industry than these approaches. Acceptance of this proposal would unify and simplify the control approach used for *V.p.* and *V.v.* and provide a level playing field for industry.<br><br>FDA intends to provide additional information in support of this Proposal in advance of the ISSC 2013 Biennial Meeting. |

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| **Cost Information (if available):** | |
| **Research Needs** | ***The purpose of this section is to allow the submitter to identify research needs associated with the proposal. Please use additional pages as necessary.*** |
| **Proposed Specific Research Need/Problem to be Addressed:**<br><br>Quantity of ice needed to cool oysters to 50F at various ambient temperatures | |
| **Please explain the relationship between the proposed research need and the program change recommended in the proposal. Support need with literature citations as appropriate.** | |
| **Estimated Cost: $** | |
| **Proposed Sources of Funding/Support:** | |
| **Time Frame Anticipated:** | |
| ***For Research Guidance Committee Use Only***<br>**Relative Priority Rank in Terms of Resolving Research Need:**<br>**☐Immediate ☐ Required ☐ Valuable ☐Important**<br>**☐Other** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-204 as substituted.<br><br>The ISSC Executive Board is tasked to work with states to seek and obtain funding for the purpose of assessing the efficacy of time and temperature controls on post-harvest Vibrio growth. Efforts shall be directed at developing robust science to define the combination(s) of prevention and post-harvest time and temperature controls that, when fully implemented, will minimize post-harvest Vibrio growth. The ISSC Executive Director, ISSC Chair, in consultation with an appropriate work group including some members of the Vibrio Management Committee shall provide guidance and administrative oversight to promote a coordinated effort among states, industry and the FDA to:<br><br>1. Assess regional and environmental differences that may better define the combination(s) of post-harvest time and temperature controls that will be most effective for a given region or state and;<br>2. Ensure that the results of research efforts will be fully considered by the membership of the ISSC.<br><br>In addition to new research activities directed at scientifically defining effective time and temperature controls, the Executive Office shall request that states and industry submit to the VMC data and information relative to efforts in their respective state associated with time and temperature assessment and control activities. This work shall be conducted over the next one to two years and the science that is generated and compiled shall be used to compose an ISSC Proposal for consideration at the 2015 biennial meeting of the ISSC for controlling the post-harvest growth of Vibrios. The Executive Board shall be briefed at each of its semiannual meetings regarding all ongoing work associated with this effort. |

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| | Additionally FDA requests that the remaining Vibrio Proposals be debated as submitted. |

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| **Proposal Subject:** | Control Plan Evaluation |
| **Specific NSSP Guide Reference:** | NSSP Guide for Control of Molluscan Shellfish, Section II. Chapter II @ .05 E. (1) and (2) |
| **Text of Proposal/ Requested Action** | Section II. Chapter II @ .05 E. (1) and (2)<br><br>E. Control Plan<br>(1) The *Vibrio vulnificus* Control Plan shall include the following:<br>(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One or more of the following triggers will be used:<br>(i) The water temperatures in the area; and<br>(ii) The air temperatures in the area; and<br>(iii) Salinity in the area; and<br>(iv) Harvesting techniques in the area; and<br>(v) Other factors which affect risk which can be used as a basis for reducing risk.<br>(b) Implementation of one or more of the following control measures to reduce the risk of *Vibrio vulnificus* illness:<br>(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70°F.<br>(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved post-harvest processing when the Average Monthly Maximum Water Temperature exceeds 70°F.<br>(iii) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Water Temperature exceeds 80°F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70°F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70°F but is less than or equal to 75°F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75°F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *Vibrio vulnificus* calculator. A state is in compliance with the NSSP when it effectively implements the controls established |

in its plan using the FDA calculator to determine the risk per serving for the established water temperatures.

(iv) The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70°F.

(2) Control Plan Evaluation

(a) The State Authority will conduct an evaluation of the plan.

At a minimum the Authority will consider:~~In consultation with FDA the Authority will evaluate the implementation and effectiveness of their Control Plan.~~:

(i) ~~Changes in t~~The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period.

(ii) Environmental changes which could affect total *Vibrio vulnificus* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) ~~The Control Plan shall be modified when the evaluation shows the Plan is ineffective, or when new information or more effective technology is available as determined by the Authority.~~For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation of Authority to determine the following:

(i) Authority compliance with *V.v.* Risk Evaluation as required in Chapter II @ .05 A.

(ii) For States requiring the development of *V.v.* Control Plans, compliance with Control Plan requirements of Chapter II @ .05 E. (1) Control Plan. The evaluation should determine:

b. Appropriate identification of trigger to determine when control measures are needed.

c. Did the Authority implement one or more of the control measures required in Chapter II @ .05 E. (1) (b).

d. For Authority implementing Chapter II @ .05 E. (1) (b) (i) or (ii), were the controls implemented adequately.

e. For Authority implementing Chapter II @ .05 E. (1) (b) (iii) (time and temperature control), did the Authority establish controls consistent with water temperature and was the FDA developed *V.v.* calculator used correctly.

(iv) For Authorities required to develop *V.v.* Contingency Plans the evaluation should determine:

c. Did the risk evaluation indicate the need for a Contingency Plan.

d. For States requiring the development of a Contingency Plan, does the plan include the regulatory steps to be implemented should the

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| | number of illnesses reach the threshold for a *V.v.* Plan.<br>(c) Should the findings of the State evaluation indicate that the Authority was in compliance with the items audited in (2) (b) and the observed risk per servings exceeded established risk per serving for one or more water temperature, the Authority will be deemed in compliance with the NSSP Model Ordinance. The FDA will include this finding in a report to the ISSC.<br>(d) The results of the State and USFDA risk per serving evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures. |
| **Public Health Significance:** | In 2001 the Interstate Shellfish Sanitation Conference (ISSC) adopted a *Vibrio vulnificus* (*V.v.*) illness reduction strategy (Proposal 00-201). This proposal established illness rate reduction goals that were based on actual *V.v.* illnesses reported by four (4) States. The implementation of this strategy has been controversial since its inception and there has never been consensus from the participants of the ISSC regarding an appropriate and effective evaluation strategy.<br><br>The initial goal of 40% was met, the 60% goal has never been achieved. The USFDA has been very critical of State efforts to meet the established illness rate reduction goal of 60% and in 2009 publicly withdrew its support for the illness rate reduction strategy, stating that the USFDA would pursue a requirement that oysters harvested from the Gulf of Mexico during periods of high risk could only be shipped in interstate commerce if post-harvest processed to reduce *V.v.* to non-detectable levels. The USFDA was requested to conduct an economic analysis of the impact of the proposed requirement. The study was conducted and the results indicated that the PHP requirement would financially devastate the industry and was not a viable option.<br><br>In 2009, the ISSC passed Proposal 09-207 which converted the illness rate reduction approach adopted in Proposal 00-201 to a risk per serving approach. The ISSC followed adoption of Proposal 09-207 with the adoption of Proposal 11-201A which established risk per serving based on the USFDA *V.v.* Risk Calculator. The established risk per servings was equivalent to the 60% illness rate reduction goal. The primary reason for ISSC adoption of Proposal 09-207 and Proposal 11-201A was the recognition of the many problems encountered by the ISSC in an attempt to use actual illness numbers to evaluate effectiveness and determine State compliance. Food safety programs have historically used illness trends to evaluate the effectiveness of food safety controls and this approved should be used rather than critiquing each illness and determine State compliance using actual reported illnesses. The adoption of Proposal 09-207 and Proposal 11-201A by the ISSC Voting Delegates was an acknowledgement of the need to move the focus of ISSC efforts to evaluation of controls rather than determinations of State compliance based on reported illnesses. This shift in focus would allow full ISSC debate of the effectiveness of controls and a collective review of the appropriateness of new controls. The results of State evaluations of *V.v.* Control Plans and USFDA evaluation of State programs would provide the ISSC with the necessary information to make decisions regarding other economically viable approaches that could be applied to the *V.v.* problem.<br><br>The language of Proposal 11-201A outlined controls that were to be implemented by |

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| | Authorities to achieve the established risk per serving levels. The proposal did not include additional control or a means of evaluating the scientific basis or the economic impacts of additional controls should States not meet the established risk per serving levels. It is unrealistic to expect States to adopt controls that are not economically feasible or have not been adopted as a control of the NSSP. This unrealistic expectation has resulted in much controversy between the ISSC and the USFDA.<br><br>The ISSC has imposed severe harvesting restrictions on the shellfish industry in Texas, Louisiana, Mississippi, Alabama, Florida, and Virginia, which has resulted in significant economic hardship to those industries.<br><br>Although not required, States were requested to implement the control of Proposal 11-201A in 2012 and the implementation of these controls were evaluated by the USFDA in 2012. The present number of *V.v.* illnesses from 2012 is much lower than in any year since 2001. Should this reduction become a trend, additional controls may not be needed. Should that not be the case, ISSC should fully debate additional controls to assure that they are scientifically based and economically feasible.<br><br>In correspondence dated May 29, 2013, the USFDA shared criteria which were developed by the USFDA for evaluating compliance with the established risk per serving outlined in Chapter II. @ .05 E. This criteria was shared with the ISSC Executive Board and Authorities for comments. Every comment received indicated disagreement with the USFDA criteria. Many commenters are concerned with the rigid evaluation approach of the USFDA. Host susceptibility issues, retail and consumer handling, and the very small number of cases continue to be issues of concern.<br><br>It appears there is agreement regarding the interpretation of the requirements outlined in Chapter II @ .05 E. (1) (a) and (b). The disagreement involves the interpretation of Chapter II @ .05 E. (2) and how the USFDA should evaluate States when the established risk per serving is not achieved for one or more water temperature periods. The USFDA has indicated it will deem a State in non-compliance if the risk per serving is not achieved for one or more water temperature periods and the State will be requested to develop an action plan. It is the opinion of States that conformance with the controls of Chapter II @ .05 E. (1) would indicate State compliance. Additionally States believe that modification of V.v. Control Plans to include additional controls should not occur without ISSC debate to allow discussion of effectiveness, scientific basis and economic feasibility. This proposal is being submitted by the VMC to allow full Conference debate regarding the intent and scope of the USFDA evaluation on State V.v. Plans. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-205 as submitted. |

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| **Proposal Subject:** | Analytical Capability and Capacity for Vibrio Testing |
| **Specific NSSP Guide Reference:** | Model Ordinance Chapter II Section @.05 and Section @.06 |
| **Text of Proposal/ Requested Action** | Chapter II Section @.05 add new G.<br><br>F. Contingency Plan<br>(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *V.v.* Control Plan.<br>(2) Contingency Plan Evaluation<br>In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.<br><br>G. States required to implement a *Vibrio vulnificus* Control Plan shall develop analytical capability and capacity to monitor *V.v.* levels with corresponding environmental data (water temperature and salinity) <u>to determine and establish baseline data.</u><br><br>Chapter II Section @.06 add new D.<br><br>C. The Time When Harvest Begins<br>For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.<br><br><u>D. States required to implement a *Vibrio parahaemolyticus* Control Plan shall develop analytical capability and capacity to monitor total and pathogenic *V.p.* levels with corresponding environmental data (water temperature and salinity) to determine and establish baseline data.</u> |
| **Public Health Significance:** | Most shellfish producing states have environmental conditions in their growing areas at certain times that present a vibrio risk. Development of the analytical capability and capacity within each state will greatly facilitate the characterization and control of this risk with regard to season, location, conditions and practices. |
| **Cost Information (if available):** | Depending on the analytical method of choice, cost per sample for one organism (either *V.v.* or *V. p.*) is ~$10-75. |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 13-206.<br>Rationale: The cost of implementation is too expensive. |

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| **Proposal Subject:** | *Vibrio vulnificus* Contingency Plan |
| **Specific NSSP Guide Reference:** | National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2011 Revision<br>Section II – Chapter II Risk Assessment & Risk Management<br>@05 D. (1), (2) |
| **Text of Proposal/ Requested Action** | D. The State shall develop a *Vibrio vulnificus* Contingency Plan should the risk evaluation indicate~~:~~<br><br>(1) Any etiologically confirmed shellfish-borne Vibrio vulnificus illness from the growing waters of that State but the number of cases does not reach the threshold established in ~~@.04~~ @.05 C~~.; and~~<br><br>~~(2) Information on Levels of Vibrio vulnificus, if available in the growing waters or in shellfish that is reasonably likely to cause an illness;~~ |
| **Public Health Significance:** | There are no known levels of Vibrio vulnificus in growing waters or in shellfish that are reasonably likely to cause illness. V. v. is present in all coastal waters in the US, there is not public health reason for States that do not have any illnesses associated with their product to have a contingency plan. Requirement of a contingency plan should not be mandatory and if needed would be included in the State's annual evaluation for Vibrio. |
| **Cost Information (if available):** | This change could possibly be a cost savings. |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-207 as submitted. |

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| **Proposal Subject:** | Shellstock Cooling Guidance |
| **Specific NSSP Guide Reference:** | Section IV. Guidance Documents, Chapter III. Harvesting, Handling, Processing, and Distribution .08 Icing, Cold Water Dips and Ice Slurries for Cooling Shellstock |
| **Text of Proposal/ Requested Action** | Section IV. Guidance Documents<br>Chapter III. Harvesting, Handling, Processing, and Distribution<br>.08 Icing, Cold Water Dips and Ice Slurries for Cooling Shellstock<br><br>For States implementing a *Vibrio vulnificus* (*V.v.*) or *Vibrio parahaemolyticus* (*V.p.*) control plan, there exist several options for temperature control to limit post-harvest *Vibrio* growth. NSSP recognized methods of temperature control include ice, mechanical refrigeration, or other approved means capable of lowering and maintaining the temperature of shellstock at 50°F (10°C) or less. The State Shellfish Control Authority is responsible for approving measures used by industry to control shellstock temperature for the purpose of complying with the State's *Vibrio* Control Plan. The desired outcome of temperature control is to inhibit bacterial growth after harvest.<br><br>In the past, questions have arisen regarding the efficacy and safety of icing as a means of controlling the post-harvest growth of *Vibrio* species. Icing has long been recognized in the NSSP as an acceptable and effective means of temperature control. The use of ice for temperature control is found throughout the NSSP Model Ordinance (MO). MO Chapter VIII defines temperature control as "*the management of temperature of shellstock by means of* ***ice****, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapters XI, XIII, or XIV.*" The use of ice is not a new or novel control measure and has been applied effectively by the industry for many years. Several States have established icing shellstock onboard harvest vessels and at landing as a temperature control measure with documented success. Icing shellstock for the purpose of temperature control under a State's *Vibrio* Control Plan should be considered an acceptable practice.<br><br>In the past, questions have also arisen concerning the safety of chilled water and ice slurry dips as a means for controlling post-harvest growth of *Vibrio* bacteria. Specifically questioned has been the potential for microbial contamination when oysters are submerged in cold water or ice slurries whereby repeated use of the same<br><br>cold water or ice slurry could produce a microbial rich environment, consisting not just of *Vibrio* species but of fecal coliforms and other bacteria as well. Properly maintained, the water temperature of the dip should be sufficiently cold to retard the growth and proliferation of most microorganisms. Maintaining the dip at or below 50°F (10°C) will inhibit growth and proliferation of bacteria. To help ensure that cold water and ice slurry dips do not become overloaded with mud, sediment, and debris, in accordance with MO requirements, shellstock are to be washed making them reasonably free of mud, bottom sediments, and other material. Once removed from warm harvest waters and washed, shellstock placed in cold water or ice slurries close their bivalve shells, cease filtering activity, and can remain closed for extended periods. They generally remain closed and inactive throughout the time needed to cool while held in cold water dips and ice slurries, thereby minimizing the potential for the introduction of *Vibrio* species or other microorganisms during these cooling |

processes. Additionally, except for naturally occurring bacteria such as *Vibrio* species, oysters harvested from approved areas should not carry with them, or their sediments, pathogens of public health concern. Furthermore, the use of warm water dips for heat shock, which is typically followed by a cold water dip to rapidly bring shellstock temperature back down, has been a long recognized and accepted NSSP process. The proper use of dips for rapidly cooling shellstock at harvest can be an effective measure to controlling post-harvest growth of *Vibrio* species and should not introduce other public health risks when practiced safely under the approval of the State Shellfish Control Authority. For these reasons, the use of cold water baths and ice slurries should be considered acceptable for controlling the post-harvest growth of *Vibrio* species.

Studies conducted by Texas A&M and the University of Florida Oyster Industry Laboratory have demonstrated that rapid cooling using ice and ice slurries not only prevents the growth of *Vibrio* bacteria, but can reduce *Vibrio* levels in Gulf oysters with no significant increase in oyster mortality. Methods varied from ice slurry dips to ice packing followed by cold storage, using both shucked and live product. The study data clearly suggests that icing and ice slurry dips are effective in maintaining and even reducing *V.v.* and *V.p.* levels after harvest. Additional preliminary studies performed by FDA at the Gulf Coast Research Laboratory in Dauphin Island, Alabama demonstrated no evidence of significant increases in levels of *Vibrio* species, fecal coliforms and other bacterial indicators resulting from ice slurry use.

To help ensure the safe use of ice and rapid cooling dips, the following should be considered:

(1) Water used to wash shellstock free from mud, sediment and other material should be from a potable water source or from a growing area classified as Approved and open to harvest.
(2) Ice should be made from a potable water source and properly protected from contamination prior to use.
(3) Water used in cold water or ice slurry dips should be from a potable water source or from a growing area classified as Approved and open to harvest.
(4) When icing shellstock, proper drainage should be provided to allow gravimetric removal of melting ice.
(5) When recirculated cold water is used to cool shellstock, water temperature should be monitored to ensure proper cooling and water quality should be monitored to ensure against impairment from sediment and particulate buildup due to extended use, which could result in a microbial or filth hazard.
(6) When cooling shellstock in cold water dips, water should be monitored to ensure proper cooling temperatures are maintained and to ensure against impairment from sediment and particulate buildup due to extended use.
(7) When ice slurries are used to rapidly cool shellstock, water quality should be monitored to ensure against impairment from sediment and particulate buildup due to extended use.

As with all control measures, the State must approve prescribed applications for use. It remains the State's responsibility to ensure the safety and efficacy of approved procedures for temperature control. It follows that before approving any system for temperature control, whether onboard harvest vessels, at landing sites, or in processing plants, prospective systems for cooling should be evaluated by the State. Existing guidelines on the safety and quality of ice and water used for cooling

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| | shellstock should suffice to address recent questions. Additionally, consultation with FDA Regional Shellfish Specialists or CFSAN is always available to States needing further guidance. |
| **Public Health Significance:** | The proposed guidance document provides specific information regarding the safe and effective use of ice, ice slurries and cold water dips for rapidly cooling shellstock. These cooling techniques provide an excellent strategy for effectively controlling post-harvest growth of *Vibrio spp.* When properly applied, these rapid cooling strategies have even been shown to reduce Vibrios to levels below those at the time of harvest. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-208 as submitted. |

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| **Proposal Subject:** | Re-submerging of shellstock |
| **Specific NSSP Guide Reference:** | Model Ordinance Chapter V Section @.01 Paragraphs A and C; and Chapter V Section @.02 Paragraph B: Model Ordinance Chapter I. Purpose and Definitions |
| **Text of Proposal/ Requested Action** | Chapter I. Purpose and Definitions<br>Definitions.<br>Add new definition –<br><br>(92) Re-submerging means the process of short term submersion of shellstock in an approved growing area following initial harvest for purposes of reducing naturally occurring bacterial pathogens to background levels.<br><br>Renumber existing definitions 92 through 121.<br><br>Chapter V. Shellstock Relaying and Re-submerging<br><br>Section @.01 Paragraph A.<br>A. The shellstock:<br>(1) ~~u~~Used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;<br>(2) Used in re-submerging activities is harvested from growing areas classified as approved or conditionally approved;<br>B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;<br>C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms ~~in the water~~, or naturally occurring pathogens such as *Vibrio* spp., or poisonous, or deleterious substances that may be present in shellstock to occur; and<br><br>Section @.02 Paragraph B<br><br>A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.<br>B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay or re-submerging activity:<br>(1) The bacteriological quality of each shellfish species is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or<br>(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or~~.~~<br>(3) The level of naturally occurring pathogens (*Vibrio* spp.) in each shellfish species is the same level of naturally occurring pathogens as that of the same species already present in the approved or conditionally approved area. |

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| **Public Health Significance:** | States that have a significant vibrio risk as determined by risk assessment have adopted requirements to limit the time between harvest and initial refrigeration. Compliance with these time restrictions have created operational difficulties for various industry sectors and re-submerging oysters after initial harvest is being pursued as a means to mitigate vibrio growth during temperature abuse. However, the effectiveness of this approach for reducing Vibrios has not been demonstrated for the various approaches and practices that have been employed or proposed. This practice has the potential to greatly increase vibrio levels, especially if the oysters are unable to purge due to handling issues, transfer to different environmental conditions, gear type or over stacking. If the oysters are unable to pump, Vibrios will continue to grow at a rate determined largely by water temperature. While re-submerging has great potential to reduce vibrio levels, the best practices need to be determined and implemented. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends referral of Proposal 13-209 to an appropriate committee as determined by the Conference Chairman. |

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| **Proposal Subject:** | Aquaculture Facilities Inspections |
| **Specific NSSP Guide Reference:** | Section II Chapter VI Shellfish Aquaculture Requirements for the Authority<br>@ .01 General |
| **Text of Proposal/ Requested Action** | C. The Authority shall inspect commercial land-based aquaculture systems facilities at least every six months, and open-water grow-out operations, floating aquaculture operations, remote setting operations and nursery systems at least annually. The Authority shall at a minimum:<br><br>1) inspect operator records to verify that appropriate permits are up to date and operational plans are being adhered to, and<br>2) determine if seed from restricted or prohibited waters are being cultured and if appropriate safeguards are in place to ensure such seed are purged for an appropriate period of time before harvest. |
| **Public Health Significance:** | The term "aquaculture systems" is undefined. The Model Ordinance only requires the inspection of "floating aquaculture and land-based aquaculture facilities." Bottom culture aquaculture operations do not appear to require inspections at all. The Model Ordinance does not describe what an inspector should examine when inspecting aquaculture systems.<br><br>For open water and floating aquaculture grow-out operations in open and conditionally approved waters, an annual inspection should be adequate to ensure that appropriate permits are in place and operational plans are being adhered to. Additional inspections do not ensure a higher level of public health protection.<br><br>Land-based molluscan aquaculture includes hatcheries (exempt), larval-setting operations (that should also be exempt), and nursery systems for very small seed. Grow-out systems do not currently exist because pumping costs are prohibitive, however should economics change to make such systems affordable, these systems will be functionally similar to wet storage systems and will justify more extensive (twice annual) monitoring |
| **Cost Information (if available):** | Since the current Model Ordinance does not describe what an inspection of an aquaculture system entails, it is difficult to determine the cost impact of this change. |
| **Action by Task Force II 2013** | Recommends referral of Proposal 13-210 to an appropriate Committee as determined appropriate by the Conference Chairman with instructions that the Committee address the definition of aquaculture, the frequency of inspection, the items that should be inspected, and the nature of an operational plan. |

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| **Proposal Subject:** | Bulk tagging for transport to original dealer (harvest control) |
| **Specific NSSP Guide Reference:** | Section II Chapter VIII F. (7) |
| **Text of Proposal/ Requested Action** | Bulk tagging for transport to original dealer<br><br>Section II – Chapter VIII Control of Shellfish Harvesting p. 73<br><br>F. Shellstock Identification.<br><br>(7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities.<br><br>(a) When shellstock are harvested from one harvest area on a single day by a single harvester or aquaculture leaseholder, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, in a single boat, vehicle, conveyance or other container and the unit tagged with a single tag in accordance with the requirements of Section- .02 F.<br><br>(b) In addition to the information required in Section .02 F. the unit tag shall also include:<br><br>(i) A statement that "All shellstock containers in this lot have the same harvest data and area of harvest"; and<br><br>(ii) Number of individual containers in the unit or an estimate of the total weight, volume or count. |
| **Public Health Significance:** | When a harvester is transporting shellstock from a single harvest area or lease to a dealer, and all of the shellstock is from the same harvest area and harvested on the same date, a single tag describing the entire lot should suffice.<br><br>This practice should only be allowed as long as there is no opportunity for co-mingling, and no question about the origin or harvest date of individual containers within the boat's, vehicle's or conveyance's cargo area.<br><br>This practice will eliminate repetitive, time consuming, wasteful and unnecessary paperwork, thereby improving compliance. |
| **Cost Information (if available):** | Will save approximately 25 cents in labor and tag costs for every duplicate tag eliminated, potentially saving hundreds of dollars per year. |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-211 as submitted. |

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| **Proposal Subject:** | Tagging requirements for wet stored shellstock |
| **Specific NSSP Guide Reference:** | Section II Chapter X, .05, B., 2., d. |
| **Text of Proposal/ Requested Action** | Shellstock Identification requirements for wet stored shellfish<br><br>**Section II – Chapter X General Requirements for Dealers** p. 83<br>**.05 Shellstock Identification.**<br><br>A. General.<br><br>B. Tags.<br>(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:<br>(a) The dealer's name and address.<br>(b) The dealer's certification number as assigned by the Authority.<br>(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.<br>(d) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, the dealers lot designation, the letter "W" and the final harvest date which is the date removed from wet storage.<br><br>-----AND-----<br><br>**Section IV. Guidance Documents - Chapter III. Harvesting, Handling, Processing, and Distribution** p. 321<br><br>**.04 Shellstock Tagging.**<br>Except for shellstock that originated from a depuration-processor, shellstock transported across State lines and placed in wet storage must include the following information on its shipping tag after removal from wet storage:<br>• All information required on a dealer's tag as specified above; and<br>• The statement that "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO AND WAS REMOVED FROM WET STORAGE ON (DATE)" |
| **Public Health Significance:** | Having multiple dates on the dealer's tag has proven to be confusing to the customers. The CFIA has chosen to avoid this confusion by listing date of removal from wet storage and listing that as the harvest date. This is the most efficacious method of clarifying the issue of when the shellfish comes out of the water which determines the shelf life of the product.<br><br>Trace back is still dependent upon the Dealer's inventory control and the ability of the wet storage operator to distinguish which lots of shellfish came from which harvest area on certain dates and which lots went to which customers on which ship dates. This information trail is still vital to the trace back and will still be required.<br><br>This will make Canadian CFIA wet storage tagging requirements consistent with those of the ISSC and maintain true equivalence between the two programs. This is important since products from both countries compete directly in the marketplace. |
| **Cost Information** | Trace back will still be dependent on the wet storage operator's ability to maintain |

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| **(if available):** | accurate inventory records demarcating which lots from which harvest areas and dates were shipped to which customers on which dates. Requiring this information on the tags as well only adds a layer of complexity and confuses the customers. |
| **Action by 2013 Task Force II** | Recommends referral of Proposal 13-212 to an appropriate Committee as determined by the Board Chairman with instructions to the Committee to try and find ways to increase foreign compliance on this issue. |

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| **Proposal Subject:** | Review of .03 Requirements for Dealers |
| **Specific NSSP Guide Reference:** | NSSP Guide Model Ordinance Chapters XI, XII, XIII, XIV, and XV<br>Section .03 |
| **Text of Proposal/ Requested Action** | Subsequent to the adoption of Federal Regulation 123 Fish and Fishery Products, the ISSC incorporated HACCP principles into the NSSP Model Ordinance. In this transition many items which were not associated with Critical Control Points or sanitation were incorporated into the .03 Section of Chapters XI, XII, XIII, XIV, and XV. Many of these controls are not critical to ensuring that shellfish are safe for human consumption. While Section .03 does have a few important requirements, most are not essential to the effectiveness of the NSSP and should be eliminated. The submitter requests that a committee be appointed to determine which of the requirements presently included in the .03 Sections of Chapters XI, XII, XIII, and XIV should be retained and recommend an appropriate placement for incorporating these requirements into Section .01 and .02. The remaining requirements should then be deleted. The effort would make inspection, standardization, and evaluation of State programs more relevant to assuming that shellfish are safe for human consumption. |
| **Public Health Significance:** | The proposal would streamline inspection, standardization, and State evaluations. These changes would allow public health officials to focus on requirements that address illness risk. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-213 as submitted. |

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| **Proposal Subject:** | Shellstock Storage and Handling |
| **Specific NSSP Guide Reference:** | Section II, Model Ordinance, Chapter XI. .03 F. (1), Chapter XIII. .03 F. (1), Chapter XV. .03 F. (1) |
| **Text of Proposal/ Requested Action** | **Chapter XI. .03 F. (1)**<br>F. Shellfish Storage and Handling.<br>~~The dealer shall:~~<br>~~(1) Assure that shellstock is:~~<br>~~(a) Reasonably free of sediment [O]; and~~<br>(b) Culled; ~~[K]~~<br>(1) ~~(2)~~ Assure…<br><br>**Chapter XIII. .03 F. (1)**<br><br>F. Shellfish Storage and Handling.<br>(1) The dealer shall~~:~~<br>(a) Assure that shellstock is~~:~~<br>(i) ~~A~~a~~=~~live~~;~~ .[K]<br>~~(ii) Reasonably free of sediment [O]; and~~<br>(iii) Culled; [K~~]~~<br>(2) The dealer shall…<br><br>**Chapter XV. .03 F.**<br><br>F. Shellfish Storage and Handling.<br>(1) ~~The dealer shall assure that shellstock is:~~<br>~~(a) Reasonably free of sediment [O]; and~~<br>(b) Culled; [K]<br>.02 01 Shellstock shall be stored… |
| **Public Health Significance:** | There is no documented public health significance to the condition of shellstock in relation to whether it is culled or muddy in the plant. Muddy shellstock may cause cleaning issues during processing and if the plant or equipment is not cleaned adequately should be debited for those conditions and not for the fact that the shellstock are muddy in storage or during processing. Culling is routine plant activity as product is handled and relates to quality control not public health. Muddy shellstock and culling should not be separate debit items during plant inspections. |
| **Cost Information (if available):** | No cost involved |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 13-214.<br>Rationale: This issue is adequately addressed in the NSSP Model Ordinance. |

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| **Proposal Subject:** | Ice Production, source of ice |
| **Specific NSSP Guide Reference:** | 2011 NSSP MO Chapter XI .02. (A.)(2.), Chapter XII .02 (A.)(2.), Chapter XIII .02 (A.)(2.), Chapter XIV .02 (A.)(2.), Chapter XV .02 (A.)(2.) AND Chapter XI .03 (E.)(4)(c), Chapter XII .03 (E.)(4)(c), Chapter XIII .03 (E.)(5)(c), Chapter XVI .03 (E.)(4)(c), and Chapter XV .02 (E.)(6)(c) |
| **Text of Proposal/ Requested Action** | Chapter XI. 02. (A.)(2.) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:<br>(a.) be made on-site from potable water in a commercial ice machine; [**C**] or<br>(b.) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]<br><br>Chapter XI 03. (E.)(4.) (c.) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]~~<br><br>Chapter XII. 02. (A.)(2.) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:<br>(a.) be made on-site from potable water in a commercial ice machine; [**C**] or<br>(b.) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]<br><br>Chapter XII 03. (E.)(4.) (c.) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]~~<br><br>Chapter XIII 02. (A.)(2.) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:<br>(a.) be made on-site from potable water in a commercial ice machine; [**C**] or<br>(b.) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]<br><br>Chapter XIII 03. (E.)(5.) (c.) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]~~<br><br>Chapter XIV 02. (A.)(2.) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:<br>(a.) be made on-site from potable water in a commercial ice machine; [**C**] or<br>(b.) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]<br><br>Chapter XIV 03. (E.)(4.) (c.) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]~~<br><br>Chapter XV 02. (A.)(2.) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall:<br>(a.) be made on-site from potable water in a commercial ice machine; [**C**] or<br>(b.) come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**] |

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| | Chapter XV 02. (D.)(6.) (c.) ~~Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]~~ |
| **Public Health Significance:** | Temperature control of shellstock and shucked shellfish prevents the growth of pathogenic bacteria and, as written, the only acceptable source for ice for shucker-packers, re-packers, shellstock shippers, re-shippers, and depuration processors is from an on-site commercial ice machine. In order to encourage dealers properly icing product, the allowance for sourcing ice from facilities sanctioned by the Authority or other appropriate regulatory agency is necessary. By moving the text for other than on-site ice manufacture/sourcing from the Protection from Adulterants section which is not appropriate, and moving it to the Safety of Water for Processing and Ice Production as an option for sourcing ice meets the public health mission of the NSSP. The requirement for the protection of ice, whether from an on-site or approved off-site source remains, appropriately, in the Protection from Adulteration section.<br><br>Move/remove the sourcing of ice for processing, storage, and transport of shellfish from a facility sanctioned by the Authority or the appropriate regulatory agency in the .03 section for Protection from Adulterants to the section for safety of source of ice and water under the .02 Sanitation section. |
| **Cost Information (if available):** | N/A |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-215 as submitted. |

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| **Proposal Subject:** | *Panopea generosa* as Species Exempted from Shellstock Storage Critical Control 'Point |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II. Model Ordinance<br>Chapter XIII. Shellstock Shipping .01 Critical Control Points<br>C. Shellstock Storage Critical Control Point - Critical Limits. |
| **Text of Proposal/ Requested Action** | Product intended for relay, wet storage, depuration, *mercenaria spp*. which is being cooled utilizing an Authority approved tempering plan, or geoduck clams (*Panopea generosa*) are exempt from the requirements listed above in .01.B.(4) with implementation beginning January 1 after proposal adoption. |
| **Public Health Significance:** | The geoduck clam (*Panopea generosa* – until 2010 referred to by the extinct clam name of *Panopea abrupta*) is a fishery dominated by the native tribes in Washington. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. @.01.B. (4) would cause significant mortality in this product. There is no record of geoduck clams being associated with vibriosis; laboratory testing of geoduck clams in 2007 by DOH revealed no detected presence of *Vibrio parahaemolyticus*. |
| **Cost Information (if available):** | There is no projected cost for this proposal. There is expected cost savings associated with this proposal due to the high loss of product expected with compliance. |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-216 as substituted.<br><br>(5) Product intended for relay, wet storage, or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria sp* which are being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above.**[C]**<br><br>Implementation is to begin three (3) months after concurrence by FDA. This achieves the goal of not waiting until publication of the new NSSP Guide and takes into account the requirement that FDA approve all changes adopted at the ISSC Biennial Meeting, while minimizing unnecessary loss of geoduck product.<br><br>**Substitute Public Health Significance**<br>The geoduck clam (*Panopea generosa*) was until 2010, referred to by the extinct clam name of *Panopea abrupta*. The optimum handling, keeping and shipping temperature is 47° to 52° Fahrenheit (8.3°-11.1° Celsius). The lower temperatures contained in the shellstock critical control point at Chapter XIII. .01. B. (4) would cause significant mortality in this product. |

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| **Proposal Subject:** | Shellfish Storage and Handling-Shucking |
| **Specific NSSP Guide Reference:** | NSSP Guide for the Control of Molluscan Shellfish, Section II.<br>Chapter XIII. .03 F. (6) (c) |
| **Text of Proposal/ Requested Action** | Section II. Chapter XIII. .03 F.<br><br>(6) All shellstock obtained from a licensed harvester shall be<br>(a) Adequately iced;<br>(b) Placed in a storage area maintained at 45° F (7.2° C); or<br>(c) Processed within two (2) hours of receipt. **If the dealer is shucking quantities of shellfish that cannot be shucked within two (2) hours the Authority may allow a dealer to exceed the two (2) hours. To exceed the two (2) hour requirement the dealer must reduce the time from harvest exposure to receipt at the dealer facility. The dealer must not exceed the total amount of time between harvest exposure and shucking [Chapter VIII. @ .02 A. (3)] and the two (2) hour requirement of Chapter XI. .03 F. (11). These time/temperature modifications must be included in the dealers HACCP Plan.** **[$S^{C/K}$]** |
| **Public Health Significance:** | |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 13-217.<br>Rationale: This issue is adequately addressed in the Model Ordinance |

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| **Proposal Subject:** | Accounting of Shellfish Quantities in Depuration Facilities |
| **Specific NSSP Guide Reference:** | NSSP Section II Model Ordinance Chapter XV. Depuration |
| **Text of Proposal/ Requested Action** | Chapter XV. Depuration<br><br>Requirements for the Authority<br><br>[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this Chapter in regulation.]<br><br>A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:<br>(1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;<br>(2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;<br>(3) Approve the design and construction of the depuration facility or activity including subsequent changes;<br>B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.<br>C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.<br>D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.<br>E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:<br>(1) Inspection reports and reviews of the plant performance in accordance to Section D. (above);<br>(2) Current Depuration Plant Operations Manual for each dealer (Section.03).; and<br>(3) Precise inventory control and bio-security, before and after the depuration process.<br>F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.<br><br>Chapter XV. Depuration<br><br>Requirements for the Dealer<br><br>.03 Other Model Ordinance Requirements<br><br>I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible |

to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:

(1) Introduction including:
  (a) Status of document (to create, revise, or update DPOM);
  (b) Ownership and principal(s) involved with operation of facility;
  (c) Address and phone number of owners and principles; and
  (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.

(2) Description of the facility including:
  (a) Site plan drawings;
  (b) Facility layout including detailed schematic of the entire depuration system;
  (c) Schematic drawing of process;
  (d) Product flow diagram showing product movement through facility (may be combined with Section 01 B. (3);
  (e) Statement that construction materials and fabrication will meet the requirements of Section 03 E. (1) and (2); and
  (f) Schematic of seawater delivery and distribution system.

(3) Design specifications of depuration unit including:
  (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
  (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
  (c) Shellfish containers construction and material meets Section .04 and Section .08 of this Chapter; and
  (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.

(4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);

(5) Depuration process monitoring including:
  (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
  (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
  (c) Process water monitoring protocol for physical and chemical parameters; and
  (d) Data analysis and evaluation.

(6) Standard Operating Procedure for:
  (a) Receiving and holding;
  (b) Washing, culling, and placement of undepurated product in process tanks;
  (c) Depuration unit operation;
  (d) Monitoring of depuration unit operation;
  (e) Removal of depurated product from process tanks;
  (f) Storage parameters and procedures;

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| | (g) Labeling/tagging procedures;<br>(h) Plant cleaning and sanitation; and<br>(i) Data analysis.<br>(j) Recall procedures.<br>(7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.<br>(a) Shipping and receiving records;<br>(b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;<br>(c) Maintenance and Sanitation Log(s);<br>(d) Laboratory records; and<br>(e) Counts of shellfish before and after the depuration process, specifically including the total number, or volume of shellfish. Shellfish sold by the piece after depuration shall be counted by the piece upon landing. If sold by volume, then volume would be recorded at landing. |
| **Public Health Significance:** | To ensure that all product delivered to the depuration plant is properly placed into the depuration process it is critical that counts and amounts of shellfish are properly counted and volumes properly assessed upon receipt. Harvester allegations of missing or diverted shellfish imply that some product may be diverted from the process. |
| **Cost Information (if available):** | Since plant operators typically count product after the process, counting at the beginning instead should not impact the cost of the operation. |
| **Action by 2013 Task Force II** | Recommends no action on substitute Proposal 13-218.<br>Rationale: There is no public health issue. |

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| **Proposal Subject:** | Depuration Equipment Sanitizing Requirements |
| **Specific NSSP Guide Reference:** | NSSP Guide for the Control of Molluscan Shellfish, Section II. Chapter XV. .02 B. (2) |
| **Text of Proposal/ Requested Action** | (2) Cleaning and sanitizing of food contact surfaces.<br><br>(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Depuration tanks and trays are not considered to be food contact surfaces.<br><br>The dealer shall:<br>(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K]<br>(ii) ~~Wash, rinse and s~~Sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]<br>(iii). Wash and rinse equipment at the end of each day. [K]<br><br>(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]<br><br>(c) Shellstock depuration tanks shall be cleaned ~~and sanitized~~ on a regular schedule as part of a plant sanitation standard operating procedure. [K] |
| **Public Health Significance:** | The present language of Chapter XV requires depuration processors to wash, rinse and sanitize equipment prior to beginning each day's operation. This proposal seeks to eliminate the need to wash and rinse at the start of each day and allow this at the end of each day's operations. In addition, this proposal will eliminate the need to sanitize equipment such as depuration tanks and shellfish trays used in depuration. Equipment used in depuration does not present a risk of food borne illnesses. The Depuration process is intended to eliminate pathogens and is highly monitored and it is not reasonably likely for product contamination to occur as a result of the condition of equipment. During the depuration process, process water is *continuously* sanitized and depuration waters are monitored on a daily basis with lot testing requirements as an additional safeguard.<br><br>Other processes such as land based wet storage operations do not have specified cleaning and sanitizing requirements specified by the Model Ordinance. Depuration equipment is no more likely to cause illness than wet storage equipment. The depuration process is more highly controlled and tested than wet storage; therefore depuration equipment is less likely to contaminate product than equipment used in wet storage. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-219 as amended.<br><br>(2) Cleaning and sanitizing of food contact surfaces. |

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| | (a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. Depuration tanks and trays are not considered to be food contact surfaces.<br><br>The dealer shall:<br>(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses; [K]<br>(ii) Sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]<br>(iii). Wash and rinse equipment at the end of each day. [K]<br><br>(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]<br><br>(c) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K] |

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| **Proposal Subject:** | PHP Validation and Verification Costs |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II. Chapter XVI. Post-Harvest Processing |
| **Text of Proposal/ Requested Action** | In 2003 the Interstate Shellfish Sanitation Conference (ISSC) acknowledged the public health benefits of Post-Harvest Processing (PHP) to reduce *Vibrio vulnificus (V.v.)* levels in shellfish. The Conference has continued to support the voluntary adoption of PHP by the shellfish industry. In subsequent years the Conference adopted validation and verification procedures for dealers utilizing PHP. The cost of validation and verification continues to be an obstacle for many smaller dealers. The procedure should be reviewed to identify ways to reduce costs while continuing to provide a reasonable level of public health protection |
| **Public Health Significance:** | |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends referral of Proposal 13-220 to an appropriate committee as determined by the Conference Chairman. |

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| **Proposal Subject:** | *Vibrio parahaemolyticus* Control Plan for Hard Clams (*Mercenaria Mercenaria)* |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section @.06 *Vibrio parahaemolyticus* Control Plan |
| **Text of Proposal/ Requested Action** | @.06 *Vibrio parahaemolyticus* Control Plan<br><br>A. Risk Evaluation.<br>Every State from which oysters or hard clams (*Mercenaria Mercenaria*) are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)<br>(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State; and<br>(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and<br>(3) The water temperatures in the area; and<br>(4) The air temperatures in the area; and<br>(5) Salinity in the area; and<br>(6) Harvesting techniques in the area; and<br>(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.<br>B. Control Plan<br>(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or<br>(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:<br>(a) Waters bordering the Pacific Ocean: 60°F.<br>(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.<br>(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters or hard clams harvested from those areas.<br>(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;<br>(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other |

areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster and/or hard clam harvest;

(ii) Restricting oyster and/or hard clams harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iii) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(iv) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(v) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters or hard clams and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to

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| | PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.<br>(d) Evaluate the effectiveness of the Plan.<br>(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.<br>(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.<br>C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. |
| **Public Health Significance:** | Hard clams, of the species *Mercenaria mercenaria*, from the Atlantic coast have been increasingly implicated in *Vibrio parahaemolyticus* illnesses in recent years and now constitute a significant risk second to oysters with regard to reported illnesses in the US. In order to reduce the incidence of *Vibrio parahaemolyticus* illnesses, States with a history of illnesses associated with hard clams harvested from their growing areas, and states where a risk evaluation has determined that the risk of *Vibrio parahaemolyticus* is reasonably likely, need to develop and implement a *Vibrio parahaemolyticus* control plan aimed at reducing the incidence of illness to no more than 1 illness in 100,000 servings. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-221-L as amended.<br><br>@.06 *Vibrio parahaemolyticus* Control Plan<br><br>A. Independent Species Specific Risk Evaluation.<br>Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)<br>(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State; and<br>(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and<br>(3) The water temperatures in the area; and<br>(4) The air temperatures in the area; and<br>(5) Salinity in the area; and<br>(6) Harvesting techniques in the area; and<br>(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.<br>B. Independent Species Specific Control Plan<br>(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably |

likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or

(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(a) Waters bordering the Pacific Ocean: 60°F.

(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.

(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters or hard clams harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;

(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster and/or hard clam harvest;

(ii) Restricting oyster and/or hard clams harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iii) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or

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| | sampling, as determined by the Authority in consultation with FDA;<br>(iv) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;<br>(v) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.<br>(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters or hard clams and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.<br>(d) Evaluate the effectiveness of the Plan.<br>(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.<br>(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.<br>C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.<br><br>Implementation will be delayed until June 1, 2015, for States not involved with *V.p.* outbreaks in clams to allow adequate time for States to work with industry to develop enforceable clam tempering plans. |

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| **Proposal Subject:** | *Vibrio parahaemolyticus* Control Plan Water Temperatures |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section<br>@.06 *Vibrio parahaemolyticus* Control Plan<br>B. Control Plan (2) |
| **Text of Proposal/ Requested Action** | @.06 *Vibrio parahaemolyticus* Control Plan<br><br>A. Risk Evaluation.<br>Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)<br>(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and<br>(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and<br>(3) The water temperatures in the area; and<br>(4) The air temperatures in the area; and<br>(5) Salinity in the area; and<br>(6) Harvesting techniques in the area; and<br>(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.<br>B. Control Plan<br>(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or<br>(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:<br>(a) Waters bordering the Pacific Ocean: 60°F.<br>(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.<br>(c) Waters bordering the Atlantic Ocean (NY and north): 60°F.<br>(~~c~~d) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.<br>(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;<br>(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have |

been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster harvest;

(ii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iii) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(iv) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(v) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

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| | (f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.<br>C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. |
| **Public Health Significance:** | Presently Chapter II. Section @.06 B. (2) does not include a water temperature for New York and north. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-222-L as submitted. |

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| **Proposal Subject:** | *Vibrio parahaemolyticus* Control Plan Risk Per Serving |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Chapter II Risk Assessment and Risk Management Section<br>@.06 *Vibrio parahaemolyticus* Control Plan<br>New D. |
| **Text of Proposal/ Requested Action** | @.06 *Vibrio parahaemolyticus* Control Plan<br><br>A. Risk Evaluation.<br>Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)<br>(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and<br>(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and<br>(3) The water temperatures in the area; and<br>(4) The air temperatures in the area; and<br>(5) Salinity in the area; and<br>(6) Harvesting techniques in the area; and<br>(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.<br>B. Control Plan<br>(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or<br>(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:<br>(a) Waters bordering the Pacific Ocean: 60°F.<br>(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81°F.<br>(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.<br>(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;<br>(ii) In concluding that the risk is not reasonably likely to |

occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include: (i) Post harvest processing using a process that has been validated to achieve a two (2) log reduction in the levels of total *Vibrio parahaemolyticus* for Gulf and Atlantic Coast oysters and a three (3) log reduction for the Pacific Coast oysters;

(i) Closing the area to oyster harvest;

(ii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iii) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(iv) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60°F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(v) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *Vibrio parahaemolyticus* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating

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| | compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.<br>(d) Evaluate the effectiveness of the Plan.<br>(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.<br>(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.<br>C. The Time When Harvest Begins For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.<br><br>B. <u>States implementing a Vibrio parahaemolyticus Control Plan shall determine the level of protection afforded by calculating the observed risk per serving based on the number of annual illnesses attributed to shellfish harvested from the state and the state's annual oyster and/or hard clam production. Modify the Control Plan when the observed risk per serving is greater than 1 illness per 100,000 servings.</u> |
| **Public Health Significance:** | In the absence of a requirement for states to determine the observed risk per serving, it is not possible to verify that the level of protection offered by state Control Plans is consistent with the level of protection (≤1 illness per 100,000 servings) intended by time and temperature controls as defined by the *Vibrio parahaemolyticus* risk calculator. Requiring states to determine the observed risk per serving using annual illness data and annual production data will allow the ISSC to gauge the success of state control plans and engage states in developing additional controls where necessary. During periods of unacceptable risk, further restrictions on time and temperature controls, or other equivalent measures, should be considered to reduce risk to an acceptable level. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends referral of Proposal 13-223-L to an appropriate committee as determined by the Conference Chairman. |

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| **Proposal Subject:** | Implementation Date for Harvester and Dealer Training Requirements |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II<br>Chapter VIII Control of Shellfish Harvesting .01 General A. and<br>Chapter X General Requirements for Dealers .04 Certification Requirements |
| **Text of Proposal/ Requested Action** | Change the implementation date for the harvester and dealer training requirements adopted in Proposal 09-212 from January 1, 2014 to January 1, 2015. |
| **Public Health Significance:** | In 2013 the ISSC Voting Delegates adopted Proposal 09-212 which requires training for harvesters and dealers. The Voting Delegates established an implementation date of January 1, 2014, for these training requirements. States are not prepared at this time to implement these requirements and a later implementation date is being suggested. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends no action on Proposal 13-224-L.<br><br>Rationale: Task Force II did not agree that a change to the implementation date was appropriate. |

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| **Proposal Subject:** | Guidance for Submission of Post-Harvest Process Validation Studies |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Model Ordinance Chapter XVI. and Section IV Guidance Documents Chapter IV. |
| **Text of Proposal/ Requested Action** | Add a new Section .05 Template for Submission of Post-Harvest Process Validation Studies as follows:<br><br>In the *National Shellfish Sanitation Program* (NSSP) *Model Ordinance Chapter XVI: Post Harvest Processing* (PHP) it states that if a dealer elects to utilize a PHP for the purpose of making safety added labeling claims they must conduct a validation study to demonstrate the ability of the PHP to reduce the target pathogen(s) to acceptable levels. Specifics on target levels and approved methods of detection for pathogens are found in the Model Ordinance. All laboratory analysis must be performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents. Results of the validation study should be submitted in the following format for review and consideration by state and federal shellfish control authorities. For validation of *Vibrio vulnificus* or *Vibrio parahaemolyticus* methods, checklist may be used as a guide.<br><br>1) TITLE OF PHP METHOD VALIDATED<br>2) SUMMARY<br>3) OBJECTIVES (Study Purpose)<br>a) Detailed description of the PHP method validated.<br>b) Target pathogen(s) and prescribed reduction.<br>4) METHOD OF ANALYSIS<br>a) Post-Harvest Process description.<br>i) Identify temperatures, weights or other pertinent information for the PHP method. Methods of mollusk preparation, for example acclimation to temperature or salinity, include all details. All variables that could affect the outcome of the PHP must be detailed.<br>ii) Identify number of animals used in study and number of trials performed.<br>b) Laboratory: (Pre and post processing pathogen measurement and description of analytical procedure)<br>i) Initial pathogen levels and pathogen detection model: microbiological or chemical analysis.<br>(1) How was initial pathogen load achieved, i.e. naturally occurring population, inoculation or thermal abuse.<br>(2) Provide adjusted Geometric Mean (AGM) calculations and unit of measure appropriate for target (i.e.: MPN/g for Vibrio or coliforms, CFU/100g for Elevated Temperature Coliform Plates (ETCP fecals).<br>(3) Analytical methodology used for pathogen quantification and confirmation. This method must be recognized in the NSSP Guide for the Control of Molluscan Shellfish (Accepted methods listed in Section IV. Guidance Documents Chapter II.10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.) |

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| | ii) Post Process Product Analysis: microbiological or chemical analysis<br>(1) Quantify pathogen level(s) in processed product utilizing the same analytical method used to attain initial load.<br>c) Validation Outcome:<br>i) Provide specific information regarding outcome measurements. Metric used to validate method (these will vary depending on targeted pathogen and are located in the Model Ordinance). Documentation that process achieved target reduction.<br>5) RESULTS<br>a) Graphs, tables and charts outlining the validation study results.<br>i) Data from validation demonstration; levels achieved in post process.<br>ii) Pathogen measurements (for example: AGM interval, grams per tube and the number of positive tubes as per the guidance document for verification/validation).<br>6) CONCLUSIONS:<br>a) Demonstrate reduction of the target pathogen to NSSP established standards.<br>7) APPENDIX<br>a) Tables or graphical interpretations of data.<br>8) OPTIONAL INFORMATION<br>a) If appropriate, include optional items such as interpretation of confounding factors or applicable industry limitations.<br>b) Acknowledgements, for example funding sources, technical help or bibliography. |
| **Public Health Significance:** | The purpose of this proposal is to provide guidance for dealers conducting post-harvest processing validation studies for the purposes of labeling shellfish as outlined in Model Ordinance Chapter XVI. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force** | Recommends adoption of Proposal 13-225-L as submitted. |

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| **Draft- Checklist for Submission of Post-Harvest Process Validation Studies for *Vibrio vulnificus* and *Vibrio parahaemolyticus*** | |
| | **Explanation of PHP Method Validated** |
| | 1. Method name |
| | 2. Specific information about machinery, equipment, or supplies necessary to perform the method of PHP is provided |
| | 3. Standard operating procedures: Detailed description of the PHP method validated is provided |
| | 4. What are the specific issues that must be accounted for during processing? For example, is there a limit to number of shellfish, spacing, hold times that are considered part of the |
| | 5. Internal quality control measures for equipment calibration, maintenance, repair and for performance checks are explained. |
| | **Objectives to be Accomplished** |
| | 1. Does the process reduce the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30MPN/gram) and achieve a minimum 3.52 log reduction? |
| | 2. Was the process validated by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s) in a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens. |
| | **Method of Analysis** |
| | 1. Was laboratory analysis performed by a laboratory that has been evaluated by FDA or an FDA certified LEO and found to "conform" or "provisionally conform" with the requirements of the National Shellfish Sanitation Program (NSSP) Model Ordinance Chapter III and supporting Guidance Documents?<br>2 |
| | 2. Are all variables that could affect the outcome of the PHP identified: temperatures, weights or other pertinent information? |
| | **Pre Processed Samples to attain initial levels** |
| | 1. Microbiological testing for initial levels was done by a 3-tube MPN using appropriate dilutions (10-1 to 10-6). |
| | 2. Was the initial level of Vibrios for each lot of shellfish used in the validation 10,000 MPN per gram or greater based on the adjusted geometric mean (AGM) of the MPNs/g of four samples? |
| | 3. How were the zero hour levels achieved: through naturally occurring Vibrio levels in shellfish, time/temperature abuse, inoculation? (Inoculation is not preferred) |
| | **Enumeration of or Processed Samples** |
| | 1. Does a sample consist of a composite of 10 to 12 oysters processed at one time from one |
| | 2. Is there data on ten processed samples obtained on each of three processing days (total of 30 samples)? |
| | 3. Microbiological testing for processed samples was done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish. |
| | 4. Are only analytical methods to determine Vibrio levels previously endorsed by the ISSC as indicated in Model Ordinance Chapter XVI. Post-Harvest Processing? |
| | 5. Was microbiological testing for processed samples done with a single dilution five-tube MPN, inoculating with either 0.01 g or 0.1 g of shellfish per tube? |
| | 6. **For the process to be validated, no more than three samples out of 30 may fail**. Failure is based on the Guide for the Control of Molluscan Shellfish 2009 Section IV. Guidance Documents Chapter IV. Naturally Occurring Pathogens .04 Post Harvest Processing (PHP) Validation/Verification Guidance for *Vibrio vulnificus* and *Vibrio parahaemolyticus.* |

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| **Proposal Subject:** | Guidelines for Primary Certified Shellfish Processors on Using Controls for Irradiation of Containers of Molluscan Shellfish Pre-labeled with Vibrio Reduction Language |
| **Specific NSSP Guide Reference:** | Section IV. Guidance Documents<br>Chapter III. Harvesting, Handling, Processing, and Distribution |
| **Text of Proposal/ Requested Action** | Add New Section .09<br><br>.09 Irradiation Pre-labeling Guidance<br><br>This document provides guidance to primary certified shellfish processors involved in transferring pre-labeled shellfish to be processed at irradiation post-harvest process (PHP) facilities.<br><br>Vibrios are highly sensitive to ionizing radiation. The National Shellfish Sanitation Program (NSSP) recognizes Vibrio reduction processes such as irradiation and provides general requirements for dealers using them. For irradiation the following guidelines provide additional detail:<br><br>• All shellfish irradiation facilities and shellfish processors using an irradiation facility to PHP shellfish must be recognized by their State Shellfish Control Authority (SSCA) as a certified PHP facility and comply with NSSP Model Ordinance Chapter XVI.<br><br>• Irradiation facilities must utilize a process that has been validated in accordance with the NSSP to achieve a reduction of *V.v.* and/or *V.p.* to less than 30 MPN/g. The process shall not irradiate shellfish to an absorbed dose of greater than 5.5 kGy, as provided by 21 CFR § 179.26. While the size of the container of shellfish does not affect the ability of the process to provide the proper dose of irradiation to all shellfish in a process batch, once a process has been validated it is essential that all containers be of uniform size with the same number of containers on each pallet. This is also important for purposes of product tracking and control. Each processor wishing to use an irradiation facility that has already been recognized and validated in accordance with the NSSP does not have to revalidate the irradiation process being used. Further, if a NSSP recognized irradiation facility conducts verification sample testing, processors using that facility to PHP shellfish may use those verification sample results to fulfill their NSSP verification requirements.<br><br>• The shellfish processor and the irradiation facility must have implemented a Hazard Analysis Critical Control Point (HACCP) plan approved by the respective SSCAs for the PHP process that ensures the target pathogen(s) in shellfish are consistently reduced to levels recognized as safe in the NSSP Model Ordinance.<br><br>• Once the irradiation process is completed containers of irradiated shellfish should be segregated from other shellfish or seafood products.<br><br>Under 21 CFR § 179.26(c), molluscan shellfish that are irradiated must bear a specific logo and a statement specifying that the shellfish have been treated by irradiation or treated with radiation. However, PHP irradiation facilities that irradiate shellfish may not have the capability to also label the shellfish as irradiated; such facilities can only irradiate the shellfish, not label them. As such, the primary processor may pre-label the pallets of shellfish as irradiated and may also provide a |

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| | statement detailing Vibrio reduction.<br><br>For dealers who ship shellfish to an irradiation facility in containers that have been pre-labeled as irradiated with vibrio reduction information the following guidelines provide additional detail:<br><br>• A signed agreement should be in place between the irradiation facility and the primary certified shellfish dealer specifying the post office addresses of each party and outlining the specifications needed to ensure that the pre-labeled containers of shellfish do, in fact, undergo the validated irradiation process set forth within the agreement.<br><br>• Both the primary shellfish dealer and the irradiation facility must each have an implemented HACCP plan to ensure that shellfish pre-labeled as irradiated undergo the validated irradiation process set forth in the agreement.<br><br>• The agreement should provide for transport of the shellfish in sealed trucks and the transport should be secured with a tamperproof seal at the primary certified dealer and a record should be made of the seal number.<br><br>• The agreement should also establish that the oyster shellstock is washed, sorted, and placed into pre-labeled containers by the primary certified shellfish dealer.<br><br>• The agreement should specify how to palletize pre-packaged and pre-labeled oyster containers.<br><br>• Pallets of oyster containers shall be clearly labeled with the words "TO BE IRRADIATED."<br><br>• The number of pre-labeled containers should be documented in a HACCP record and in an additional record to be provided to the operator at the irradiation facility. This transport should be limited to pallets of shellfish to be irradiated and no other seafood or shellfish products.<br><br>• When the transport arrives, the irradiation facility operator may remove the seal, record the number of containers, verify the number of containers in the transport matches the record provided by the primary certified dealer and then record the number of containers in the irradiation facility's HACCP record.<br><br>• The irradiation facility operator shall record all other required HACCP receiving critical limit information in HACCP records.<br><br>• Irradiated shellfish shall be placed in cooler storage or on transports maintained at the appropriate temperature (cooler maintained at 45 degrees and transport pre-chilled to 45 degrees).<br><br>• Irradiated shellfish shall be segregated from other seafood or shellfish products.<br><br>• The irradiation facility shall also have implemented a HACCP plan that includes the critical control points for receiving, the irradiation process, and |

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| | refrigerated storage. |
| **Public Health Significance:** | Vibrio bacteria are predominately found in estuarine environments and naturally present in most shellfish. Most cases of disease attributed to Vibrio species are associated with the consumption of raw molluscan shellfish, particularly raw oysters and hard clams. Vibrio-related sicknesses can cause severe illness, including mortality. The most common Vibrio species found in shellfish are *Vibrio vulnificus* (*V.v.*) and *Vibrio parahaemolyticus (V.p.*). *V.v.* is associated with 95 percent of all seafood-related deaths in the United States. Thus, Vibrio species in uncooked molluscan shellfish provide a significant public health risk which may be minimized by enabling industry to streamline this process for irradiation PHP. |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-226-L as submitted. |

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| **Proposal Subject:** | Eliminate Requirements for the Authority to Retain Records of a Trade Secret or Proprietary Nature. Such records to be available at the dealer's place of business during normal business hours. |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II. Model Ordinance<br>Chapter V. Shellstock Relaying @.01 General D.;<br>Chapter V. Shellstock Relaying @.02 Contaminant Reduction B.; and<br>Chapter XV. Depuration Requirements for the Authority E. (1) and (2) |
| **Text of Proposal/ Requested Action** | Chapter V. @.01<br>D. The ~~Authority~~ dealer shall retain records covering all aspects of the establishment of the heat shock process.<br><br>Chapter V. @.02<br>B. The person responsible for conducting the study ~~Authority~~ shall retain the written study report indefinitely.<br><br>Chapter XV. Requirements for the Authority<br>~~E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years: (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above); (2) Current Depuration Plant Operations Manual for each dealer (Section .03).~~<br><br>Delete all other elements that require the Authority to keep on file or retain records of a trade secret or proprietary nature. Such records will be required to be maintained at the dealer facility and available to the authority for review during normal business hours. |
| **Public Health Significance:** | There is no cost to the Authority to eliminate these requirements. |
| **Cost Information (if available):** | Freedom of Information Act (and similar state act) requests can be time consuming, costly, and detract from public health activities of the Authority. Industry should be required to make records available to the Authority at the dealer's facility during normal business hours. Requiring the Authority to collect and maintain such records that may be subject to Freedom of Information Act release undermines the relationship of industry and regulators and further serves as a disincentive for businesses to conduct research, innovate and develop new products, processes and procedures |
| **Action by 2013 Task Force II** | Recommends adoption of Proposal 13-227-L as amended.<br><br>Chapter V. @.01<br>D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.<br><br>Chapter V. @.02<br>~~B. Authority shall retain the written study report indefinitely.~~<br><br>Chapter XV. Requirements for the Authority<br>E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the |

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| | period of five years: (1) Inspection reports and reviews of the plant performance in accordance to Section D. (above); ~~(2) Current Depuration Plant Operations Manual for each dealer (Section .03).~~<br><br>~~Delete all other elements that require the Authority to keep on file or retain records of a trade secret or proprietary nature. Such records will be required to be maintained at the dealer facility and available to the authority for review during normal business hours.~~ |

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| **Proposal Subject:** | Outbreaks of Shellfish Related Illness |
| **Specific NSSP Guide Reference:** | NSSP Guide Section II Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority and Section IV. Guidance Documents Chapter V Illness Outbreaks and Recall Guidance |
| **Text of Proposal/ Requested Action** | Model Ordinance Chapter I Shellfish Sanitation Program Requirements for the Authority @.01 Outbreaks of Shellfish-Related Illness.<br><br>D. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:<br><br>(1) Each consumer's food history;<br>(2) Shellfish handling practices by the consumer and/or retailer;<br>(3) Whether the disease has the potential or is known to be transmitted by shellfish; and<br>(4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.<br><br>NOTE: Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses will be defined as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period<br><br>E. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:<br><br>(1) Conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.<br>(2) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.<br><br>F. When the investigation outlined in Section .02 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:<br><br>(1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status (unless more than thirty (30) days have passed since the last reported illness and no additional illnesses have occurred;<br>(2) Notify receiving states, the ISSC and the FDA Regional Shellfish Specialist that a potential health risk is associated |

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| | with shellfish harvested from the implicated growing area;<br>(3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and<br>(4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products (unless more than thirty (30) days have passed since the last reported illness [associated date of harvest] and no implicated product is likely to remain in the market place).<br><br>Guidance Documents Chapter V Illness Outbreaks and Recall Guidance<br>.01 Guidance for Investigating an Illness Outbreak and Conducting Recall<br><br>A. Requirements for the Authority<br><br>When an illness outbreak has occurred, immediate closure of the implicated growing area(s) will significantly reduce the chance of additional illnesses during the investigatory process. Immediate closure for the purposes of this Guidance Document means within twenty-four (24) hours of notification of the illness (NSSP Model Ordinance Chapter IV. @.03 A. (1)). If a preliminary investigation reveals that the growing area is not implicated, an immediate closure is not necessary. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2011). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2011).<br><br>In determining the appropriateness of harvest area closures in response to sporadic cases of *V.p.* illness, the Authority will:<br><br>(1) Define Illness outbreaks involving sporadic cases of *Vibrio parahaemolyticus* illnesses as two (2) or more persons not from the same household becoming ill from shellfish from the same harvest area within a seven (7) day period.<br>(2) Not institute a harvest closure if more than thirty (30) days has passed since the last reported illness.<br>The Authority should assign an Illness Investigation/Recall Coordination Lead (the Lead) for the agency to be listed on the ISSC website as the agency contact person. The Lead will be the agency contact for the duration of the event.<br><br>During and after the immediate closure, the Authority must be in the process of investigating, evaluating and conducting increased surveillance. Immediate closures will not always result in an immediate recall of product. It is imperative that the Authority communicate with State Epidemiologists, local health officials, pertinent State agencies, industry and others as necessary to complete a thorough investigation. |

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| | Additionally, immediate closures may not be necessary if the investigation reveals that the illness outbreak was caused by a specific activity by a single entity which can be controlled through a product recall and an immediate corrective action in the processing or transport of product.<br><br>An illness outbreak investigation must include an evaluation of the health hazard presented and consideration of the following factors, including but not limited to:<br><br>1. Immediately send staff members out to perform growing area reconnaissance,<br>2. Review documentation of the information supporting growing area classification, review environmental sample trends, secure additional shellstock and/or water samples if necessary<br>3. Review toxin sample trends, sampling protocol and supporting information for Biotoxin closures, secure additional shellstock and/or water samples if necessary<br>4. Interview local sources regarding any anecdotal or factual information on the origin of contaminants (large passenger vessels, point and non-point sources),<br>5. Immediately send staff members out to interview certified dealer(s), restaurant staff members or retail establishment staff members to secure additional details regarding tagging, record keeping, refrigeration temperatures, handling practices, shipping and receiving information and where and from whom the shellfish products were purchased, name and telephone number of contact person,<br>6. When possible, interview harvesters in the area of concern to determine handling practices and specific harvest area(s)<br>7. Determine the identity of the product involved, the extent of distribution of implicated product, total amount of the suspected product, total amount in distribution chain, distribution information and proposed recall strategy.<br><br>A product recall may not be appropriate when an illness outbreak investigation reveals the following, including but not limited to:<br><br>1. When the etiological and epidemiological evidence confirms that shellfish from a specific growing area or lease area are the cause of the illnesses<br><br>2. When it has been determined that a specific process conducted by a dealer is the cause of the illnesses<br><br>A product recall may not be appropriate when an illness outbreak investigation reveals, but is not limited to, the implicated product is no longer available in the market. It is reasonable for the Authority to conclude that a recall is not necessary when more than thirty (30) days has passed since the last reported case of illness.<br><br>When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of |

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| | product initiated, and the problem immediately corrected. Under these circumstances no closure of the growing waters is warranted in accordance with NSSP Model Ordinance, Chapter II. @.01 D. |
| **Public Health Significance:** | |
| **Cost Information (if available):** | |
| **Action by 2013 Task Force II** | At the request of the submitter Proposal 13-101 was discussed in conjunction with Proposal 13-202. See Task Force II action on Proposal 13-202. |